

Appl. No. 10/774,393
Amendment dated: January 4, 2005
Reply to OA of: October 7, 2004

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-39(cancelled).

40(previously presented). A canister comprising an aluminium can closed with a metering valve and containing a pharmaceutical aerosol formulation which comprises:

- (i) fluticasone propionate at a concentration of 0.04 to 0.1% w/v;
- (ii) 1,1,1,2-tetrafluoroethane (HFA 134a) as propellant; and
- (iii) ethanol wherein the concentration thereof is 5 to 30% w/w, characterised in that the fluticasone propionate is completely dissolved in the formulation.

41(previously presented). A canister according to claim 40 wherein the formulation is free of surfactant.

42(previously presented). A canister according to claim 40 wherein the concentration of ethanol is 5 to 20% w/w.

43(previously presented). A canister according to claim 41 wherein the concentration of ethanol is 5 to 20% w/w.

44(previously presented). A canister according to claim 40 wherein the concentration of ethanol is 10 to 20% w/w.

45(previously presented). A canister according to claim 41 wherein the concentration of ethanol is 10 to 20% w/w.

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46(previously presented). A canister according to claim 40 wherein the formulation comprises:

- (i) fluticasone propionate;
- (ii) 1,1,1,2-tetrafluoroethane (HFA 134a) as propellant;
- (iii) a low volatility component to increase the mass median aerodynamic diameter (MMAD) of the aerosol particles on actuation of the inhaler; and
- (iv) ethanol wherein the concentration thereof is 5 to 30% w/w, characterised in that the fluticasone propionate is completely dissolved in the formulation.

47(previously presented). A canister according to claim 46 wherein the formulation comprises a low volatility component which is glycerol, propylene glycol or polyethyleneglycol.

48(previously presented). A canister according to claim 47 wherein the low volatility component is glycerol.

49(previously presented). A canister according to claim 46 wherein the low volatility component is present in an amount of 0.5 to 3% w/w.

50(previously presented). A canister according to claim 48 wherein the low volatility component is present in an amount of 0.5 to 3% w/w.

51(previously presented). A canister according to claim 40 wherein the formulation contains fluticasone propionate as the only medicament.

Claim 52(cancelled).

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53(previously presented). A canister according to claim 46 wherein the formulation contains fluticasone propionate as the only medicament.

54(previously presented). A canister according to claim 40 wherein the metering valve is capable of delivering a volume of 50 μ l or 63 μ l.

55(previously presented). A canister according to claim 41 wherein the metering valve is capable of delivering a volume of 50 μ l or 63 μ l.

56(previously presented). A canister according to claim 46 wherein the metering valve is capable of delivering a volume of 50 μ l or 63 μ l.

57(previously presented). A canister according to claim 51 wherein the metering valve is capable of delivering a volume of 50 μ l or 63 μ l.

58(previously presented). A canister according to claim 40 wherein the metering valve is capable of delivering a volume of 50 μ l.

59(previously presented). A canister comprising a can closed with a metering valve and containing a pharmaceutical aerosol formulation which comprises:

- (i) fluticasone propionate at a concentration of 0.04 to 0.1% w/v;
- (ii) 1,1,1,2-tetrafluoroethane (HFA 134a) as propellant; and
- (iii) ethanol wherein the concentration thereof is 5 to 30% w/w, characterised in that the fluticasone propionate is completely dissolved in the formulation.

60(previously presented). A canister according to claim 59 wherein the formulation is free of surfactant.

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61(previously presented). A canister according to claim 59 wherein the concentration of ethanol is 5 to 20% w/w.

62(previously presented). A canister according to claim 60 wherein the concentration of ethanol is 5 to 20% w/w.

63(previously presented). A canister according to claim 59 wherein the formulation comprises:

- (i) fluticasone propionate;
- (ii) 1,1,1,2-tetrafluoroethane (HFA 134a) as propellant;
- (iii) a low volatility component to increase the mass median aerodynamic diameter (MMAD) of the aerosol particles on actuation of the inhaler; and
- (iv) ethanol wherein the concentration thereof is 5 to 30% w/w, characterised in that the fluticasone propionate is completely dissolved in the formulation.

64(previously presented). A canister according to claim 63 wherein the low volatility component is glycerol.

65(previously presented). A canister according to claim 63 wherein the low volatility component is present in an amount of 0.5 to 3% w/w.

66(previously presented). A canister according to claim 59 wherein the metering valve is capable of delivering a volume of 50µl or 63µl.

67(previously presented). A canister according to claim 63 wherein the metering valve is capable of delivering a volume of 50µl or 63µl.

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68(previously presented). A metered dose inhaler which comprises a canister according to claim 40 fitted into suitable channelling device.

69(previously presented). A metered dose inhaler which comprises a canister according to claim 41 fitted into suitable channelling device.

70(previously presented). A metered dose inhaler which comprises a canister according to claim 46 fitted into suitable channelling device.

71(previously presented). A metered dose inhaler which comprises a canister according to claim 51 fitted into suitable channelling device.

72(previously presented). A metered dose inhaler which comprises a canister according to claim 59 fitted into suitable channelling device.

73(previously presented). A metered dose inhaler which comprises a canister according to claim 60 fitted into suitable channelling device.

74(previously presented). A metered dose inhaler which comprises a canister according to claim 63 fitted into suitable channelling device.